EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MEDRAD, INC. Plaintiff, vs TYCO HEALTHCARE GROUP LP, MALLINCKRODT INC., LIEBEL-FLARSHEIM CO., and NEMOTO KYORINDO CO., LTD. Defendants.	)	CIVIL ACTION NO. 01-1997-GLL Judge Gary L. Lancaster

DEFENDANTS' PRETRIAL STATEMENT

Pursuant to the Case Management Order (Doc. No. 182) and W.D.PA.LR. 16.1.4.B, defendants Tyco Healthcare Group LP, Mallinckrodt Inc., Liebel-Flarsheim Company (referred to collectively as "L-F") and Nemoto Kyorindo Co., Ltd. ("Nemoto"), submit their Pretrial Statement comprising:

I. Narrative Statement of Facts (Portions containing information designated "Confidential" have not been submitted for publicly accessible electronic filing pending ruling on Defendants' Motion for Leave to File Supplemental Pretrial Statement Under Seal)

II. Defenses to Damages Claims

III. Witness List

IV. Deposition Designations, Objections and Counter-Designations to Plaintiff's Deposition Designations

V. Exhibit List

VI. Legal Issues to be Addressed at the Final Pretrial Conference

VII. Copies of Expert Disclosures Made by Defendants (Those expert reports identified as "Confidential" have not been submitted for publicly accessible electronic filing pending ruling on Defendants' Motion for Leave to File Supplemental Pretrial Statement Under Seal)

I. NARRATIVE STATEMENT OF FACTS

A. Introduction

This case involves claims by Medrad, Inc. ("Medrad") that L-F and Nemoto are infringing claims 8, 9, 22, 25-28, 30, 31 and 33-39 of U.S. Patent No. Re 37,602 ("the '602 re-reissue patent") through the manufacture, offer for sale, sale and/or importation of the Optistar MR and Optistar LE injectors. The '602 re-reissue patent is a reissue of U.S. Patent No. Re 36,648 ("the '648 reissue patent"), which is, in turn, a reissue of U.S. Patent No. 5,496,036 ("the '036 patent").

The '602 re-reissue patent is invalid because the basis Medrad stated for seeking reissue of the '648 reissue patent is not authorized under 35 U.S.C. § 252, which permits the reissue of patents only for limited purposes. The '602 reissue patent is also invalid because Medrad failed to comply with the rules governing reissue of patents, and in particular the requirement of 37 C.F.R. §1.175(b)(1) that an applicant file a supplemental declaration verifying that the errors in the original patent arose without deceptive intent.

The claims are also invalid because Medrad failed to disclose the best mode known to the named inventors for practicing the claimed inventions as required by 35 U.S.C. § 112, ¶ 2. Further, the asserted claims of the '602 reissue patent are also invalid because the alleged inventions were known and publicly used and had been offered for sale by Medrad, more than one year before the original filing date of the '602 re-reissue patent and would have been obvious in view of voluminous prior art, including prior art created by Medrad itself. The '602 re-reissue patent is likewise unenforceable due to Medrad's inequitable conduct during the prosecution of the '648 reissue patent and the '602 re-reissue patent.

L-F and Nemoto do not infringe the asserted claims of the '602 re-reissue patent because those claims are not valid. In addition, the accused Optistar MR and Optistar LE injectors do not have a "system controller" that is located outside the shielded scanroom as required by claims 8, 9, 22, 25-28, 30, 31, 33-36, 38 and 39, nor do those injectors use fiberoptics as required by claims 8, 22, 31, and 39, or the equivalent of fiberoptics.

B. Background

1. Contrast Media Medical Injectors

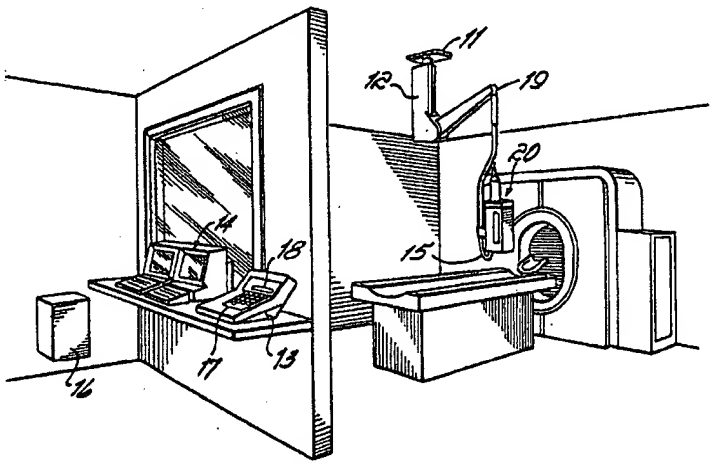
Medical injectors for injecting contrast media that enhances images taken during a variety of diagnostic procedures have been routinely used for more than 30 years. Those injectors have typically included a powerhead adapted to hold one or more syringes that contain contrast media or other fluids, one or more motors for injecting the fluid from the syringes, electronic and mechanical controls for controlling the operation of the powerhead, and a user input/output panel or console to obtain user input and to provide feedback to the user.

L-F and Medrad have been competitors in medical injectors since the 1970s. Examples of early L-F and Medrad medical injectors are the L-F Angiomat 3000 and the Medrad Mark IV (which is disclosed in U.S. Patent No. 4,006,736), both of which were used in the performance of angiographic procedures. These earlier injectors included analog controls, meaning they did not include microprocessors or use digital electronic signals. In the 1980s, both L-F and Medrad incorporated digital electronics into the controls of their medical injectors.

For example, in about 1988, L-F began selling a medical injector called the Angiomat 6000 that used digital electronics. That injector had a powerhead that held a syringe for injecting contrast media, a control box in which the electronics were located, and a console for user input and output. For ease of installation and use, the control box could be mounted

with the powerhead or in a separate location, depending on the desires of the user. Similarly, the console could be placed near the injector or at a remote location, particularly in use of the CT version (meaning computed tomography) because of the powerful X-rays used in that procedure. To enable the control box and console to be remotely located, extension cables of up to 100 feet in length were routinely used to connect the control box to the powerhead and to connect the control box to the console. In the communications between the powerhead and the control box and between the control box and the console, an RS-422 communications protocol was used because that protocol was less susceptible to electromagnetic noise and was more reliable over longer distances, such as those used in the longer extension cables sold with the Angiomat 6000. Shielded cables were used to carry the communication signals between the powerhead and control box, and between the control box and console.

L-F continued to use the RS-422 protocol and shielded cables for communications signals between the components of its medical injectors when it designed injectors introduced after the Angiomat 6000. For example, in March of 1992, L-F introduced a new power injector for the CT market known as the CT9000. As with the Angiomat 6000, the CT9000 was also sold with shielded extension cables of up to 100 feet in length for permitting remote location of the control box and the console. This is shown in Figure 1 of L-F's U.S. Patent No. 5,300,031, which is directed to L-F's CT9000 injector, in which the injector powerhead (15) is shown in the examining room, and the console (13) and control box (16) are shown in an operator's room having a viewing window. In the figure shown to the right, the cables that



communicate power and control signals between the control box and the powerhead are passed from the operator's room to the examination room through the ceiling. L-F likewise used the RS-422 communication protocol and shielded cables to connect the components of its Illumina angiographic injector, the accused Optistar MR injector introduced in 1999 and the accused Optistar LE injector introduced in 2002.

Medrad also developed newer medical injectors having digital controls, including an injector marketed in the 1980s under the name Mark V. The Medrad Mark V injector also included a turret that would accommodate two syringes, which Medrad described in a 1984 brochure as follows:

> **Flexibility because you can preload two syringes.**
>
> - Load two different contrasts, in two syringes, for one procedure. Inject one contrast, then change over to the other contrast.
>
> - Change contrasts during the procedure without stopping to change, reload, and purge syringes.
>
> * * *
>
> - Do digital flush procedures; follow contrast with saline.
>
> **Load up to 400 ml on the injector and not have to stop, reload, and purge during the procedure.**
>
> The Mark V uses either 50 or 200 ml syringes. And since it holds two syringes at once, you can preload up to 400 ml.
>
> You can also load two different contrasts (two different dilutions), and conveniently change syringes during the procedure.

2. Magnetic Resonance Imaging

Magnetic Resonance Imaging (MRI) is a diagnostic procedure that was first used in the 1970s in which a powerful magnet is used to create a weak magnetic field in a patient.

The patient is then subjected to radio waves (which alter the induced magnetic field in the patient) and, when the radio waves are withdrawn, the magnetic field in the patient returns to its original orientation and emits radio waves that are detected by a receiver and used to generate a picture of the patient.

An MRI suite typically consists of a scanroom where the MRI magnet is located and where the patient is placed during the procedure, a control room adjacent the scanroom, usually with a viewing window therebetween where the operator sits at the scanning/viewing console, and a computer room to house the system electronics in a temperature and humidity regulated environment. It is generally necessary to shield the scanroom from outside electromagnetic signals because (1) radiofrequency (RF) signals from outside the room (such as radio signals, cell phones, and electronic equipment such as computers) may interfere with the images being gathered and result in undesired artifacts, and (2) the RF signals generated by the MRI magnet can interfere with electronic equipment outside of the scanroom.

A variety of electrical equipment is present in the scanroom. This includes equipment to operate the MR imaging system itself, including associated controls such as patient bed movement controls and an emergency rundown switch to turn off the imaging system in an emergency, to monitor and communicate with the patient (such as cardiac monitors, intercoms, and a TV camera to view the patient) and to entertain the patient (such as video monitors and speakers). To prevent RF signals from entering or leaving the scanroom, all communications and power links between equipment in the scanroom (magnet, RF transmitting and receiving coils, gradient coils, table motors, etc.) and equipment in the operator's or computer room must pass through a penetration panel or filter panel or through wave guides typically integrated into the penetration panel. Shielded electrical cables have been and are used to connect this

equipment, and it was known to use the RS-422 communication protocol with such equipment.

Two alternatives are and have been available since before 1992 for transmitting communication signals into and out of the scanroom. The first is fiber optic cables, which may be passed through the penetration panel or another hole in the shield so long as care is taken to incorporate a wave guide that will prevent the transmission of RF signals through the new opening. Because the fiberoptic cable is a glass filament and the signals are in the visible portion of the spectrum, no interference-causing RF signals will be generated by the fiberoptic cable. The second alternative is to transmit signals via infrared radiation (such as has been used for over 20 years in television remote controls), which is a form of electromagnetic radiation in a frequency range outside of that detected by the MRI equipment. Such a communication link would operate by transmitting signals through the viewing window of the scanroom.

Although MRI offers a wide range of contrast, contrast media may be used to artificially increase the contrast and it was first used with MRI procedures as early as 1978. Berlex began the development of a commercial contrast media for use in MRI procedures in 1981, which was approved by the FDA in 1988.

3. Medrad's EM-1 Medical Injector

In about 1986, Medrad began the development of a contrast media medical injector for use in connection with MR procedures, which was a modification of its earlier Mark V CT injector and became known as the EM-1 injector. In 1987, Medrad sought 510(k) approval from the FDA to market its MR injector and submitted a manual for the injector to the FDA during the approval process entitled *Magnetic Resonance Injector Operation Manual* that disclosed the details of the injector. On February 5, 1988, Medrad received approval from the FDA to "begin marketing [its] device".

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Indeed, numerous papers were authored and published by users of the EM-1, all identifying the use of a Medrad MR injector. In one such article entitled *In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media* and co-authored by, among others, Bruce Rosen (one of Medrad's expert witnesses) and Sanjay Saini ("Saini Article"), an EM-1 was described as follows:

> A commercially produced mechanical injector used for contrast infusion in angiography and computed tomography (CT) (Mark V; Medrad, Pittsburgh, PA) was modified and installed in a clinical MR Imager (0.6-T Telescan superconducting magnet; Technicare, Solon, OH). The components of the MR injector consisted of a main unit, control panel, drive unit, and injector head. The main unit contained the electronics of the system and was mounted in a corner of the radio frequency (RF)-shielded room. Controls necessary to program, activate, and monitor an infusion were on the control panel. For convenience, this panel was mounted

> adjacent to the MR scanner's operating console. The control panel and main unit are connected with an interface cable.

Dr. Rosen also wrote in the Saini Article that use of the Medrad MR injector "produced no observable effect on MR images." The Court will also hear from users of the EM-1 that they too observed that the EM-1 had no effect on the MR images.

C. The '602 Re-Reissue Patent

The '602 re-reissue patent is directed to a contrast media medical injector for use in an MR environment, like Medrad's earlier EM-1 injector. As with the EM-1, the injector of the '602 re-reissue patent includes a powerhead (called an injection head unit) and a separate motor box (called an injection or head control unit) in which electric motors are located that drive the syringes of the injection head. Also as with the EM-1, the powerhead and motor box of the injector of the '602 re-reissue patent are located in the shielded scanroom, and the programming console and main unit (combined into a single system controller) are located in the control area adjacent the scanroom. Finally, the injector of the '602 re-reissue patent includes two syringes, just as did Medrad's prior Mark V injector.

Despite the fact that Medrad experienced no problems with the EM-1, which connected the equipment inside the scanroom to the equipment outside the scanroom with a shielded cable passed through the MRI penetration panel, the '602 re-reissue patent states that one problem with previous MR injector systems was "the need to provide a communications link between the externally located controller and the contrast media injectors, without introducing extraneous electromagnetic radiation." In discussing prior art contrast media injectors in MRI procedures, the '602 re-reissue patent states:

> In order to realize the full benefit of the shielded room, these systems employ a controller for the contrast media injector portion of the system which is isolated from the media injector.

> Such isolation is effected to prevent undesirable electromagnetic radiation generated by the system controller from interfering with the signals used to create the magnetic resonance images.
>
> The external, isolated location of the system controller creates various problems associated with the installation and operation of these systems. One such problem is the need to provide a communications link between the externally located controller and the contrast media injectors, without introducing extraneous electromagnetic radiation. That is, there is a need to provide electrical power supply lines for operation of the contrast media injectors and the injector control circuitry while maintaining the integrity of the electromagnetic shield.
>
> Previous attempts to solve these problems included drilling holes in the wall of the electromagnetic shield for inserting the necessary lines or, alternatively, laying the lines under a shielded floor of the imaging room. These alternatives have proven to be less than optimum, since spurious radiation arose from the presence of the various supply cables within the shielded imaging suite.

('602 re-reissue patent at column 1, lines 39-62.) To overcome these stated problems, the injector of the '602 re-reissue patent uses infrared/optical transceivers (a device that transforms electrical signals into light, and light signals into electricity) to communicate across the viewing window of the scanroom rather than electrical cables passing through the penetration panel.

> An infrared/optical communications transceiver 26 is positioned internally of the imaging room 17 at the viewing window 24 opposite the external communications transceiver 22 such that the internal and external communications transceivers communicate with each other through the viewing window with no breach of the electromagnetic shield.

('602 re-reissue patent at column 3, line 65 – column 4, line 3.) These transceivers are, in turn, connected to the motor box (injection control unit) inside the scanroom and the console (system controller) outside the scanroom by separate communication lines or links. Finally, the powerhead of the injector of the '602 re-reissue patent is powered by rechargeable batteries, and includes a pair of syringes.

The original application resulting in the '602 re-reissue patent was filed on November 26, 1993. As a result, the "critical date" for determining prior art is November 26, 1992, one year before that filing date.

D. The Asserted Claims of the '602 Re-Reissue Patent Are Invalid

1. The '602 Re-Reissue Patent is Invalid Because it was Issued in Violation of 35 U.S.C. § 251

The '036 patent, the predecessor to the '602 re-reissue patent, listed only four inventors: Arthur E. Uber, III, Seid Waddell, John Stulen, and Jon E. Manley. On February 23, 1998, Medrad filed an application with the United States Patent and Trademark Office ("PTO") seeking to reissue the '036 patent, and included reissue declarations from the named inventors stating: "We believe the original patent to be partly inoperative by reason of our claiming less than we had a right to claim in the ['036] patent," *i.e.*, based upon an alleged underclaiming error. However, several of the original claims of the '036 patent were rejected during the reissue procedure over the prior art resulting in Medrad canceling original claims 1-7 and narrowing several other claims (*i.e.*, Medrad claimed more than it was entitled – overclaiming). Medrad also amended the inventorship of the patent and added Salvatore J. Dedola and Gordon C. Newell. Medrad did not, however, file supplemental reissue declarations from the named inventors addressing the overclaiming error or the change in inventorship. The '036 patent was reissued as the '648 reissue patent.

On April 25, 2000, Medrad filed a Complaint with the U.S. International Trade Commission ("the ITC Action") alleging that certain MRI injection systems imported by L-F and Mallinckrodt from Nemoto infringed the '648 reissue patent. On September 11, 2000, the Administrative Law Judge held the '648 reissue patent invalid because the initial reissue declarations mentioned only the underclaiming error, and Medrad failed to file supplemental

reissue declarations stating that the overclaiming error and change in inventorship were made without deceptive intent. Medrad petitioned the Commission for review on October 6, 2000, which the Commission declined on February 21, 2001.

Medrad then filed an application with the PTO on November 16, 2000, this time seeking a reissue the '648 reissue patent. The reissue declarations signed by the named inventors and filed by Medrad with this application stated only that they believed the '648 reissue patent was partly inoperative for the lack of a supplemental reissue declaration. These reissue declarations did not state that the inventors believed the '648 patent was wholly or partly inoperative or invalid by reason of a defective specification or drawing, did not state that the inventors believed the '648 patent was wholly or partly inoperative or invalid by their having claimed more or less than they had a right to claim in the '648 patent, and did not state that the errors in the original patent arose without deceptive intent. Indeed, the written specification, drawings, and claims of the '602 re-reissue patent are identical to the written specification, drawings, and claims of the '648 reissue patent.

Under 35 U.S.C. § 251, a patent may be reissued only if "through error without any deceptive intent, a patent is deemed wholly or partly inoperative or invalid "by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent". Medrad failed to satisfy this statutory requirement, and the corresponding requirements under the Code of Federal Regulations, 37 C.F.R. §§ 1.175(a)(1) and 1.175 (b)(1).

2. Medrad Failed to Disclose its Best Mode

The asserted claims of the '602 re-reissue patent recite that the injection system includes a "patient infusion apparatus" (powerhead), a "communications control link" (or

variation thereof) and a battery for powering the injector. Medrad, however, did not disclose in the '602 re-reissue patent the named inventors' "best mode" of practicing those claimed features as required by 35 U.S.C. § 112.

Specifically, Medrad asserts that, in developing the injector of the '602 re-reissue patent, it had to overcome significant difficulties operating in the electromagnetic environment of MRI. It also asserts that existing CT medical injectors could not be adapted to the MR environment (even though the EM-1 injector was adapted from the Medrad Mark V CT injector) because the MR scanner must not be disturbed by ferrous materials, and must be shielded from RF interference, alternating current supplies and control systems, all of which were standard in existing medical injectors. Medrad further asserts that the medical injector of the '602 re-reissue patent was completely different from any existing power injection system, and it had a specially designed powerhead and stand that were almost completely nonferromagnetic and made from specially selected plastics. However, the '602 re-reissue patent is completely silent about a special design for the powerhead and the materials to be used in the powerhead. Similarly, although the '602 re-reissue patent states that communication lines/links connect the head control unit and system controller to the infrared/optical transceivers, it is totally silent about the form of those communication lines/links. The '602 re-reissue patent likewise states that the injector uses a rechargeable battery, but is totally silent as to the type of battery to be used. Medrad, however, had very definite and preferred forms of all of these claimed features at the time the original application resulting in the '602 re-reissue patent was filed on November 26, 1993.

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REDACTED INFORMATION – CONFIDENTIAL [redacted] The '602 re-reissue patent, however, is silent as to the materials to be used in the powerhead, the powerhead stand and the head control unit other than to say that the "drive shafts" of the flexible cable connecting the head control unit to the powerhead was to be made of "nonferrous metal such as hard brass." ('602 re-reissue patent at column 4, lines 25-26.)

The '602 re-reissue patent says even less regarding the communication link between the infrared/optical transceiver in the scanroom and the injection control unit, and the communication line between the infrared/optical transceiver outside the scanroom and the system controller. In fact, it says nothing.

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REDACTED INFORMATION – CONFIDENTIAL [redacted] Medrad sought to hide the information regarding its use of the RS-422 communications protocol when L-F subsequently requested a copy of that 510(k) file from the FDA.

Although a fiberoptic cable is used in the Spectris Solaris injector (introduced in 2002) for the communications link between the system controller and the injector, fiberoptic cables were not Medrad's preferred form of the "communication line" or "communications link" in November of 1993. Fiberoptics were mentioned in only one sentence in the '602 re-reissue patent, and then only in the summary of the invention and as "an alternative." Moreover, in 1993 fiberoptics were much more expensive, were less robust, had much lower reliability, and were more fragile than they are today. Indeed, Medrad's 510(k) filing with the FDA described only the use of the infrared/optical transceivers connected by shielded/filtered cables to the system controller and head control unit and using the RS-422 communications protocol. There was no mention of fiberoptics.

As to the rechargeable batteries, the '602 re-reissue patent says nothing more than that such batteries are to be used and that a charger is included in the system controller. Again, however, Medrad had a very definite preferred form of those batteries and the charger.

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[redacted]

3. The '602 Re-Reissue Patent Includes as Named Inventors Individuals Who Did Not Make Any Inventive Contribution

Among the named inventors of the '602 re-reissue patent are Arthur E. Uber, Seid Waddell, and Salvatore J. Dedola. Messrs. Uber, Waddell and Dedola have admitted

REDACTED INFORMATION –CONFIDENTIAL [redacted] However, during prosecution of the '648 reissue patent, Medrad conceded that the concept of an MR injector in which the motors were spaced from injector head and connected by such a flexible drive shaft was in the prior art as disclosed in the Saini Article. Specifically, Medrad canceled independent claim 1, which was directed to such an MR injector. As a result, the concept of a flexible drive shaft was not an inventive contribution, and Messrs. Uber, Waddell and Dedola are, therefore, improperly named as inventors of the '648 reissue patent and, hence, the '602 re-reissue patent.

In addition, the '036 patent did not list Mr. Dedola. Rather, he was added as a named inventor during prosecution of the '648 reissue patent when Medrad sought to "correct" the inventorship. However, Medrad did not even seek to add Mr. Dedola as an inventor until the same time that it agreed to cancel the claims directed to the flexible drive shaft, thereby admitting that Mr. Dedola, as well as Messrs. Uber and Waddell, were not properly named as inventors. Medrad had not corrected the inventorship, but rather, it had intentionally included individuals who did not provide any inventive contribution to the claims of the '648 patent, thereby rendering the '648 reissue patent, and hence the '602 re-reissue patent, invalid.

4. The '602 Re-Reissue Patent Is Invalid as the Alleged Invention was "On-Sale" Before November 26, 1992

Before November 26, 1992 (that is, more than one year before the filing date of the '602 re-reissue patent), Medrad entered into a contract to sell twenty-five injectors satisfying the asserted claims of the '602 re-reissue patent to Squibb Diagnostics, a division of E.R. Squibb & Sons, Inc. ("Squibb"), and the injector was ready for patenting.

On November 18, 1992, Medrad entered into a contract and purchase order with Squibb in which Medrad agreed to "sell" the first twenty-five injectors to third parties identified by Squibb. In exchange, Squibb agreed to pay to Medrad $450,000 within thirty days of the execution of the agreement (which it paid), and an additional $50,000 upon delivery of the fifth injector, an additional $100,000 upon delivery of the fifteenth injector, and an additional $100,000 upon delivery of the twenty-fifth injector.

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REDACTED INFORMATION –CONFIDENTIAL [redacted]

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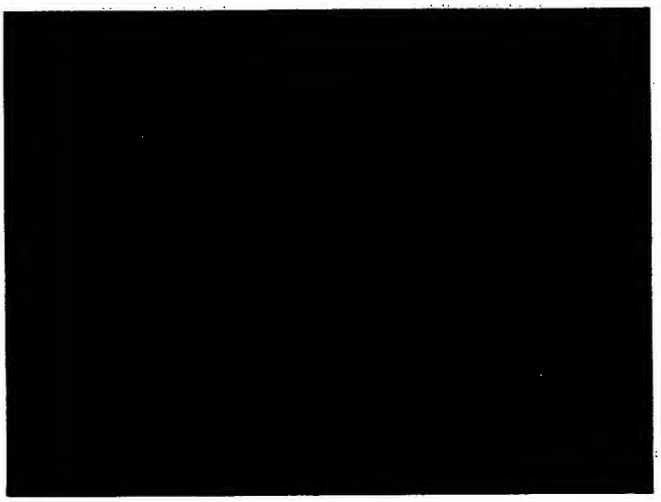

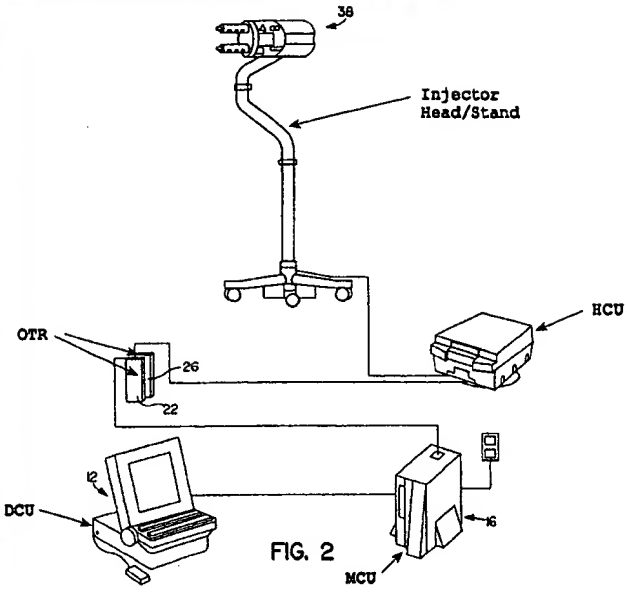

FIG. 2

The text of the Medrad 2002 NPCD also includes as much detail as that disclosed in the '602 re-reissue patent regarding the claimed elements (and was, thus, ready for patenting), as shown by the following table:

'602 Reissue Patent	[redacted]
"The MRI system includes a system controller 12 which incorporates a computer 14 and a battery charging unit 16. The system controller 12 is located externally of the imaging room 17, . . ."	REDACTED INFORMATION – CONFIDENTIAL [redacted]

'602 Reissue Patent	[redacted]
"Communication line 20, connects the system controller 12 with an external infrared/optical communications transceiver 22. . . . An infrared/optical communications transceiver 26 is positioned internally of the imaging room 17 at the viewing window opposite the external communications transceiver 22 such that the internal and external communications transceivers communicate with each other through the viewing window with no breach of the electromagnetic shield. A communications link 28 located within the shielded area connected the internal infrared/optical transceiver with a contrast media injection control unit 30."	**REDACTED INFORMATION – CONFIDENTIAL** [redacted]
"The injection control unit is powered advantageously by rechargeable battery 32. The injection control unit 30 also incorporates control circuitry which controls electric motors 35, 36 which are also located within the injection control unit. . . . The injection head unit 38 includes contrast media injection syringe and piston units 40, 42. The syringes 40, 42 are connected to the electric motors in the injection control unit by flexible mechanical drive shafts 44, 46, respectively.	**REDACTED INFORMATION – CONFIDENTIAL** [redacted]

The only detail not disclosed in the Medrad 1992 NPCD was the alternative use of fiberoptics as recited in claims 8, 22, 31 and 39. However, as set forth below, the use of fiberoptics instead of an infrared/optical transceiver would have been obvious.

5. The Asserted Claims of the '602 Re-Reissue Patent Are Invalid Over the Prior Art

a. Claims 9, 33 and 38 Are Anticipated by the EM-1 Injector

Claims 9, 33 and 38 and directed to an MR injector (claims 9 and 33), and a method of using an MR injector (claim 38), in which there is an infusion apparatus (powerhead) in the shielded scanroom, a system controller outside of the shielded scanroom and a communication control link (or variant) that is substantially non-reactive with the magnetic field of the imaging system. Claim 9 adds that the patient infusion apparatus includes "infusion apparatus control means."

Medrad's EM-1 injector, which was in public use more than five years before Medrad filed its patent application, included all of the elements of claims 9, 33 and 38 of the '602 re-reissue patent. Indeed, during prosecution of the '648 reissue patent, the Examiner concluded that the injector described in the Saini Article, which was an EM-1 injector, included every element of these claims, including contolling the injector, except communicating/controlling the injector from a room outside the shielded room through a communication/control link. Medrad, however, failed to inform that Examiner that the very EM-1 injector that was the subject of the Saini Article satisfied both of these elements. Claim 9 was narrowed during prosecution to recite that the communicating control link was "substantially non-reactive with the magnetic field of the imaging system". New claims 33 and 38 incorporated the same recitation.

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[redacted]

REDACTED INFORMATION –CONFIDENTIAL [redacted] The Saini Article itself stated that Medrad's MR injector (*i.e.*, the EM-1) "produced no observable effect on MR images."

b. Each of the Asserted Claims Would Have Been Obvious

The Saini Article and the Medrad *Magnetic Resonance Injector Operation Manual* disclose, and the Medrad EM-1 injector was, an MR injector that included an injection head and separate injection control unit (motor box) located in the shielded scanroom, a system controller located outside of the scanroom, and a communication control link connecting the system controller and the injection head/injection control unit. The '602 re-reissue patent also admits that prior art MR injectors existed that included a system controller located outside of the shielded scanroom and a contrast media controller located inside the shielded scanroom. The '602 re-reissue patent claims to have solved the alleged problems of the need to provide a communications link between the externally located controller and the contrast media injectors and to provide power to the injector without introducing extraneous electromagnetic radiation, and the need recognized in the Saini Article for "a set-up that will allow the contrast agent to be flushed out of the connecting tubing." Indeed, every element of the asserted claims of the '602 re-reissue patent is expressly disclosed in one or more of the Saini Article, the Medrad *Magnetic Resonance Injector Operation Manual* and the EM-1 injector. Medrad has admitted as much but argues that the following elements are not disclosed:

Claims 8, 22, 31 and 39 – that the communication control link is "a fiber optic" link;

Claims 9, 33 and 38 – that the communication control link or the control signals are "adapted to be substantially non-reactive with the magnetic field of the imaging system";

Claims 25 and 37 – that the at least two syringes are "operably engaged with at least one drive mechanism of the injector"; and

Claims 27, 34 and 35 – that the injector includes a battery for powering the injector and a charger to charge the battery.

These elements, however, were well known and documented in the prior art long before Medrad arrived on the scene.

i. The Use of a Fiberoptic Link or a Communication Control Link That is "Substantially Non-Reactive With the Magnetic Field of the Imaging System" Would Have Been Obvious (Claims 8, 9, 22, 30, 31, 33, 38 and 39)

The prior art disclosed three well-recognized types of communication control links (or control signals) that were "adapted to be substantially non-reactive with the magnetic field of the imaging system" (*i.e.*, a piece or complex of an apparatus for imparting or transmitting control information having minimal or no influence or effect on, and being minimally or not influenced by forces due to the MRI imaging system, which does not exclude hardwired technology). The first is shielded cables with filters to remove extraneous electromagnetic radiation; the second is a fiber optic link; and the third is to transmit the signals by infrared radiation. The prior art also provides a clear motivation to combine the use of each of these types of communication control links with the prior art Medrad EM-1 injector, the prior art MR injectors disclosed in the Saini Article and the Medrad *Magnetic Resonance Injector Operation Manual*, and the prior art MR injectors described in the '602 re-reissue patent.

Standard MRI system site planning manuals used by people installing MR suites explain that all electrical power, RF signal, and communication lines entering the shielded

scanroom must be filtered to prevent unwanted signals from entering the scanroom, and any cables entering must be RF tight (meaning shielded). Patents directed to equipment used in the shielded scanroom also disclose that cables entering the scanroom must be shielded, and the 1986 Alpha catalog explained that its highly shielded Suprashield cables should be used for high frequency digital data protection against EMI/RFI (Electromagnetic Interference/Radio-Frequency Interference). **REDACTED INFORMATION –CONFIDENTIAL** [redacted]

[redacted] Although neither the '602 specification nor claims makes any reference to an RS-422 communications protocol it was also well known, as L-F recognized in its prior art Angiomat 6000 and CT9000 injectors, that better noise immunity would be achieved through use of the RS-422 communications protocol.

In addition, because electronic noise is a very serious problem in MRI installations as is reliability of communications, for a data communications network (*i.e.*, a communication control link) to operate satisfactorily in the scanroom, it must suffer little or no degradation and produce no electronic noise. Numerous prior art patents and publications recognize, therefore, that the ultimate answer to cable emissions in control and communications links is not to use electronic signals at all but rather to use light. The prior art thus taught the use of a fiber optic cable because it insures that no electrically conductive links exist between any components inside the scanroom and any components outside the scanroom, and neither emits nor picks up electromagnetic fields. Alternatively, it has also been well known, as recognized by numerous prior art patents and publications, to transmit the control and communications signals via infrared radiation.

A person of ordinary skill in the art unquestionably would have known to use a fiber optic link (claims 8, 22, 31 and 39) or a communication control link that was (or use signals that were) "substantially non-reactive with the magnetic field of the imaging system" (claims 9, 30, 33 and 38) for any piece of equipment placed in an MR suite, including the MR imaging system itself. In other words, a person of ordinary skill in the art who set out to solve the problem of providing a communications link between an externally located controller and an injector powerhead located in the scanroom without introducing extraneous electromagnetic radiation, and who had before him the prior art, would unquestionably have used the solution that is claimed in the '602 re-reissue patent.

ii. The Use of Two Syringes Would Have Been Obvious (Claims 25, 36 and 37)

It is common medical practice, and has been since well before 1992, to follow the injection of the MR contrast media from one syringe with a saline flush from a second syringe. The quantity of contrast media used in performing MRI procedures is much smaller (only about 20-40 ml) than that used with other radiological procedures, such as CT imaging (typically 125 ml or more). MR contrast media is also much more expensive than CT imaging media. The distance between the injector and the patient in MRI procedures is also greater than in CT procedures; thus, more tubing must be used and more contrast used to fill the dead space in the tubing. As a result, it is, and has been since before 1992, very important to follow the injection of the MR contrast media with a saline flush to ensure that all of the (expensive) MR contrast media is injected into the body. Leaving only a few milliliters of contrast in the tubing as waste can constitute 10% or more of the total contrast media being used. Indeed, Berlex, the manufacturer of the first FDA approved MR contrast media, instructed users long before 1992: "To ensure complete injection of the contrast medium, the injection should be followed by a 5-

mL normal saline flush." Numerous prior art articles in medical publications likewise describe following the administration of contrast media with a saline flush.

Medrad itself recognized the desirability of an injector having two syringes, including in an MR environment, and disclosed that use in its publications. Medrad's prior art Mark V injector (upon which the EM-1 injector described in the Saini Article was based) was adapted to accommodate at least two syringes. This two-syringe arrangement was shown in Medrad's advertising in the 1980's, including one that stated the two syringes permitted the user to "Do digital flush procedures: follow contrast with saline." This two-syringe arrangement is also shown in the *Magnetic Resonance Injector Operation Manual*. Other two-syringe injectors for radiological procedures were also known and described in prior art publications.

Although the specific EM-1 injector used by Drs. Saini and Rosen did not include two syringes, the Saini Article recognized the need for a second syringe, stating that "the major impediment for routine clinical use is the absence of a set-up that will allow the contrast agent to be flushed out of the connecting tubing. Such a system is needed to reduce waste of contrast medium and to prevent its stasis in the arm."

However, a medical injector having two syringes that are operably engaged with at least one drive mechanism to perform such a saline flush was already available and shown in a prior art publication entitled "AS 200 Injector" (the front of which is shown to the right) and "AS 400 Injector", by Medex, a French company. The brochure describes that the AS 200 is an automatic injector for angiographic and CT injections,

and that the two syringes enable the radiologist to follow the injection of contrast with a douche (translated from the French "rincage"), *i.e.*, a saline flush.

The prior art clearly disclosed the desirability of and need for an injector with two syringes for use in performing MR procedures. Medical injectors having multiple syringes were already known prior to 1992, including Medrad's Mark V injector, upon which Medrad's EM-1 injector was based. Similarly, the injector disclosed in Medrad's 1987 Medrad *Magnetic Resonance Injector Operation Manual* included two syringes, although the syringes were loaded in a turret that needed to be rotated in order to inject the fluid from the second syringe. However, it is not desirable to have technicians in the MR scanroom during a procedure. Thus, it would be preferable to have an injector in which the second syringe can be operated without rotating a turret. The Medex AS 200 injector did just that. Although the AS 200 injector was an angiographic or CT injector, it would have been known that the Medex AS 200 injector could be modified for use in an MR environment by substituting nonferromagnetic materials for the standard components, just as Medrad itself did in modifying its Mark V CT injector into the EM-1 MR injector. Indeed, Medrad itself knew of the Medex AS 200 injector in 1989 and recommended it during the development of its MR injectors.

And if there be any doubt, Medrad's own Vice President of Special Projects at Medrad between 1983 and 1990 and the named inventor, who Medrad added to the '648 reissue patent when it added the two syringe claims, Gordon C. Newell, admitted that contrast agents are very expensive and that it was BGO, a "blinding glimpse of the obvious", to use two syringes on the Medrad MR injector, with the second syringe to push the expensive contrast agent with inexpensive saline.

iii. The Use of Batteries and a Battery Charger Would Have Been Obvious (Claims 27, 34 and 35)

The final element of the claims of the '602 re-reissue patent not clearly expressly disclosed or used in one or more of the Saini Article, the Medrad *Magnetic Resonance Injector Operation Manual* and the EM-1 injector, or admitted by Medrad in the '602 re-reissue patent as being present in the prior art, is the use of a battery to power the injector and a charger to charge the battery. Again, this element was already in the prior art.

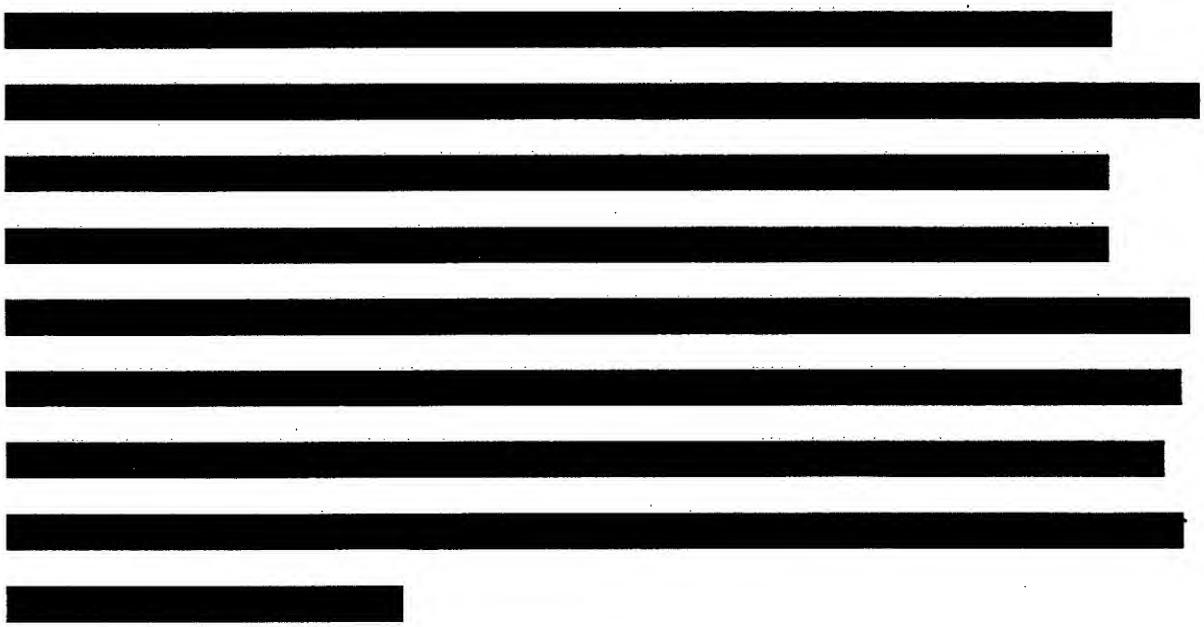
During prosecution of the '648 reissue patent, the use of a battery for powering the injector was rejected by the Examiner as obvious and the claim was cancelled. All references to a battery or battery charger are merely in dependent claims. It is clear Medrad did not dispute the Examiner's conclusion that the use of a battery and a battery charger were an obvious choice. Nor can Medrad dispute that the use of batteries in medical devices, including such devices in an MR environment and in medical injectors, is disclosed in numerous prior art patents and publications.

E. The '602 Re-Reissue Patent is Unenforceable Because of Medrad's Inequitable Conduct During Prosecution of the '648 Patent and the '602 Re-Reissue Patent

The PTO rules governing the conduct of each individual associated with the filing and prosecution of patent applications impose a duty of candor and good faith in dealing with the PTO, which includes a duty to disclose to the PTO all information known to that individual material to patentability. Information is considered to be material if it is not cumulative of information already of record, and it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim, or refutes or is inconsistent with a position the applicant takes in opposing an argument of unpatentability relied on by the PTO or

in asserting an argument of patentability. Medrad failed to fulfill that obligation during prosecution of each of the '648 reissue patent and the '602 re-reissue patent.

During prosecution of the '648 reissue patent, the Examiner rejected certain of the claims, including claim 9, over the Saini Article (which described the Medrad EM-1 injector) and L-F's U.S. Patent No. 5,300,031 ("the '031 patent"). The Examiner found that the Saini Article disclosed every element of claim 9 with the exception of placing the system controller was outside the scanroom, but he also found that the '031 patent did disclose placing the system controller outside the room. Medrad did not argue the Examiner's point but rather responded by amending the claims to recite that the communication link was "substantially non-reactive with the magnetic field of the imaging field." **REDACTED INFORMATION –CONFIDENTIAL**



Following the ITC's decision in 2000 that the '648 reissue patent was invalid, Medrad filed its second reissue application, which resulted in the '602 re-reissue patent, the claims of which are identical to those in the '648 reissue patent. During prosecution of the '602 re-reissue patent, Medrad again withheld the EM-1 from the PTO and withheld from the PTO

material information from the ITC Action. Specifically, the PTO considers information relating to invalidity defenses or charges of inequitable conduct raised in related litigation to be material to the examination of a reissue application. The PTO considers such information to be so material that the PTO's Manual of Patent Examining Procedure ("MPEP") requires that litigation materials, such as pleadings and interrogatories, be submitted to the Examiner. Although Medrad submitted to the PTO during prosecution of the '602 re-reissue patent in bulk and without explanation some of the patent prior art patents and publications raised in the ITC Action, it failed to provide any of the court papers or pleadings submitted by L-F, such as L-F's responses to Medrad's interrogatory numbers 14, 40, 41, 43 and 45, which identified and explained in detail evidence showing the invalidity of the claims over the prior art, Medrad's failure to set forth the best mode and written description requirements, and Medrad's inequitable conduct during prosecution of the '036 and '648 reissue patents. Medrad likewise failed to point out to the PTO the specific portion of the prior art that L-F had provided to Medrad and that L-F had relied upon showing invalidity of the claims, and failed to notify the PTO of the existence or substance of L-F's best mode and written description defenses.

Medrad also withheld from the PTO during prosecution of the '602 re-reissue patent information regarding the Medex AS 200 and AS 400 injectors, and Japanese Patent Publication No. 1-223943. With respect to Japanese Patent Publication No. 1-223943, Medrad submitted the reference in Japanese and an English language copy of claim 1. However, it failed to provide a copy of the translation of that reference even though it had been produced to Medrad by L-F in the ITC Action. As for the Medex materials, Medrad listed the AS2000 [*sic*] injector publication in an information disclosure statement filed with the PTO and stated that the publication had a facsimile transmission date of January 25, 1989. However, the publication was

in French, and Medrad failed to provide to the PTO a translation of the brochure that had been produced by L-F in the ITC Action. Medrad also falsely stated in the information disclosure statement that the AS2000 [*sic*] injector "concerns an automatic injector for angiographic diagnostic procedures." The AS 200 injector brochure stated that the injector was "more specifically for CT-injections," just as was the Medrad Mark V CT injector, which Medrad modified into its EM-1 MR injector as described in the Saini Article. Medrad further failed to inform the PTO that the Medex AS 200/400 injector had two syringes, each of which was engaged by its own independent drive system. As the PTO had already concluded that it would be obvious to use a CT injector (as shown in L-F's '031 patent) in an MRI environment (and, thus, would have reached the same conclusion regarding the AS 200 injector), and the PTO had found no prior art disclosing two independently-driven syringes during prosecution of the '648 reissue patent, and therefore had allowed claims 25 and 37, the withheld information concerning the AS 200/400 injector's two independently-driven syringes was material to the examination of the '602 re-reissue patent and a reasonable examiner would have wanted to consider it.

During prosecution of the '602 re-reissue patent, Medrad also provided to the PTO a highly sanitized and factually inaccurate statement regarding its development and marketing of MR injectors. As early as 1987, Medrad had decided to develop and market an MR injector. As set out above, Medrad's efforts to commercialize injectors for use in MRI procedures included its EM-1 injectors, which were a modification of its Mark V CT injector. The modifications included substituting nonferrous materials in the injector, relocating the injector drive motors from the injector assembly to a location 15-20 feet away, and providing a nonferrous flexible drive shaft between the motors and syringes. The EM-1 injectors were in clinical use from 1988 to 1996, which Medrad placed at leading hospitals in order to promote commercial interest in the

injectors. The EM-1 injectors used [redacted] cables for communicating control signals from a controller outside the scanroom to the injector inside the scanroom, which were replaced by the [redacted] system in 1992. Medrad never disclosed to the PTO its prior use of [redacted] cables in the MRI environment. **(Redacted Information Above – Confidential)**

In an information disclosure statement submitted by Medrad to the PTO on June 8, 2001, which listed 28 U.S and 24 foreign patents, 64 "Other Publications," and included a twenty-page discussion entitled "Factual Information for the Examiner's Consideration Under the 'On-Sale' Bar Codified by 35 U.S.C.§102(b)" that included 19 additional exhibits, Medrad did not even mention the EM-1 injectors. Instead, the "Factual Information" created the false and misleading impression that prior to late 1991 nothing relevant occurred except for identification of a future potential market; that only specifications existed as of April, 1992; that only concepts and proposed features existed as of November 5, 1992; that the Squibb Agreement was only a development agreement; that the injectors were to be merely provided to third parties; that the $700,000 that Squibb was to pay Medrad under their agreement was merely for the development; and that there were no product technical specifications in existence as of the November 23, 1992 critical date.

The agreement between Medrad and Squibb specified a price for each injector, and Medrad substituted the word "provides" in its "Factual Information" to the PTO for repeated references in the agreement to "sell." In addition, the development costs for the first 25 injectors to be sent to third parties were to be borne wholly by Medrad and were not reimbursed by Squibb. Rather, the $700,000 payment was to be paid in installments, the dollar amount and timing of which were keyed to the delivery of injectors. Medrad also possessed a complete set of

injector specifications that demonstrate the injector was ready for patenting at the time of the agreement between Medrad and Squibb.

F. The Optistar MR and Optistar LE Injectors Do Not Infringe Any Valid Claim of the '602 Re-Reissue Patent

1. The Versions of the Optistar Contrast Delivery System

There have been three different versions of the accused Optistar Contrast Delivery System: (1) the Optistar MR (battery-powered); the Optistar MR (AC powered); and (3) the Optistar LE.

a. Battery Powered Optistar MR Injector

The battery-powered Optistar MR injector includes 5 primary components: a powerhead, a power control, an EFI/RFI filter, a console and a battery charger. The powerhead, which is intended to be located in the scanroom near the patient, includes two piezo-electric motors that drive a pair of syringes, and is connected by a shielded electric cable to a power control that is also located in the scanroom. The power control includes a pair of batteries that provide the power for the injector components inside the scanroom and a computer processor that controls the operation of the injector system. The computer processor (CPU) in the power control is the "brains" of the injector, and all system functions are controlled and monitored by this CPU. The power control also includes the RAM and ROM of the system, a motor controller that generates the necessary drive signals for the piezoelectric motors in the powerhead and monitors the motor's speed and position, and a universal pulse processor to monitor the position and speed of the motors.

The power control communicates with the console, which is located in the operator's room, via a shielded electrical cable (just as did L-F's prior Angiomat 6000 and CT9000 injectors) from the power control to a filter installed into a hole cut into the wall of the

shielded scanroom, and another shielded electrical cable between the filter and the console. Alternatively, the electrical cable from the power control may be connected to a port on the penetration panel in the MR suite (if one is available) with the filter connected to the same port on the external side of the penetration panel and the other electrical cable then connected between the filter and the console. The console provides the user interface used to operate the injector system. Finally, a battery charger is included for charging the batteries used in the power control, which is located in the operator's room.

b. AC Powered Optistar MR Injector

The AC powered version of the Optistar MR injector is substantially similar to the battery-powered Optistar MR injector with one major exception. As with the battery-powered Optistar MR injector, the AC powered version includes 5 primary components. Three of the components are unchanged: the powerhead, the EFI/RFI filter, and the console. The power control is the same, with the exception that there is no longer any batteries. Finally, the AC powered version of the Optistar MR injector includes a power supply located in the operator's room rather than a battery charger.

Thus, unlike the battery-powered Optistar MR injector, the powerhead of the AC powered Optistar MR injector is powered not by batteries, but rather, by an electrical power supply component that is located in the control room. This electrical supply draws power from a standard AC power source (such as a traditional three-prong wall socket), and transmits the electricity to the power control in the scanroom through the EFI/RFI filter.

Because of the inclusion of the power supply, the power control located in the scanroom communicates with the console located in the operator's room through the power supply by means of a shielded electrical cable from the power control to the filter installed into a

hole cut into the wall of the shielded scanroom, and another shielded electrical cable between the filter and the power supply. A separate electrical cable connects between the power supply and the console. Alternatively, the electrical cable from the power control may be connected to a port on the penetration panel in the MR suite (if available) with the filter connected to the same port on the external side of the panel. The filter is then connected to the power control and then to the console in the same manner as before. In all other respects, the battery-powered Optistar MR injector and the AC powered Optistar MR injector operate in the same way, and the components are installed in the same way.

c. The Optistar LE Injector

The Optistar LE injector has the same 5 major components as the AC powered Optistar MR injector: a powerhead, a power control, an EFI/RFI filter, a power supply and a console. The components of the Optistar LE are installed in the same manner as the Optistar MR versions, with the components operating in a similar fashion.

As with the Optistar MR versions, the powerhead of the Optistar LE, which is intended to be located in the scanroom near the patient, includes two piezo-electric motors that drive a pair of syringes. The powerhead is connected by a shielded electric cable to the power control that is also located in the scanroom. As in the Optistar MR, the power control of the Optistar LE is the "brains" of the system and includes five main assemblies: an interconnect assembly, a power board, a CPU board, a communication board and a driver board. The CPU board controls and monitors all system functions. The driver board controls the piezoelectric motors on the powerhead by converting pulses generated by the CPU into motor drive signals. The communication board carries all non-motor signals between the power control and the powerhead cable, carries the electrical power from the power supply to the on/off switch and to

the interconnect assembly, and converts the transmit and receive signals from the CPU into signals to the console. The interconnect board provides the connections for all of the components of the power supply. Finally, the power board converts the power received from the power supply into the forms needed for the system. Also as in the Optistar MR versions, the console of the Optistar LE provides the user interface. Because of the inclusion of the power supply, the power control communicates with the console in the same way discussed above with respect to the AC powered version of the Optistar MR injector.

2. Claims 8, 9, 22, 25-28, 30, 31, 33-36, 38 and 39 Are Not Infringed Because Neither the Optistar MR Nor the Optistar LE Has a System Controller Located External to the Shielded Room

Each of claims 8, 9, 22, 25-28, 30, 31, 33-36, 38 and 39 of the '602 reissue patent recite that the system includes a "system controller" that is located outside of the shielded room. The Court has construed a system controller as "a hand-operated or automatic device used to regulate or guide the operation of a MRI patient infusion system." The Optistar MR and Optistar LE injectors do not include such a "system controller" that is located external or outside the shielded scanroom.

The component of the Optistar injectors that "regulates or guides" the operation of the infusion system is the power control, which is located inside the scanroom, and not the console, which is located outside the scanroom. The power control and console serve two distinct functions in the Optistar injectors, and these distinctions are detailed in a Software Requirements document prepared with respect to the Optistar LE injector. These requirements apply equally to the Optistar MR injectors as the software for the power control of the Optistar LE is unchanged from that of the Optistar MR versions except for minor changes that do not affect the overall functions performed by the two components.

This Software Requirements documents differentiates between the console software (and its accompanying functions), which transmits user inputs to the power control and receives information from the power control that is displayed for the user, and the power control software (and its accompanying functions), which verifies input from the console, operates the injector motors, distinguishes among the various sizes of syringes used on the injectors, monitors and reacts to pressure in the two syringes, monitors and reacts to the motor encoder signals, and generates alarm messages when abnormal operations occur that are then displayed by the console. Thus, the operation of the injector motors, monitoring of and reaction to the system functions, and generation of warning messages are controlled by the power control, which is located in the shielded scanroom. The console is incapable of causing the operation of the actual infusion apparatus. This is done solely through commands from the power control to the powerhead.

The consoles of the Optistar MR and Optistar LE injectors are input devices, not system controllers. Although the console allows the input of information which helps to define the MRI infusion procedure, the console does not guide or regulate the operation of the injector system. This is done by the power control located inside the shielded scanroom. The power control has the only software and the only CPU that communicates directly with the powerhead. It is the power control that sends commands to the powerhead to move the motors, it is the power control that monitors the location of the rams of the injectors and reacts to that location, it is the power control that monitors the pressure in the syringes, and it is the power control that directs the console to display warning messages. The console is not capable of doing any of these functions, only of reacting to the commands that the power control has sent to it.

3. Claims 8, 22, 31 and 39 Are Not Infringed Because Neither the Optistar MR Nor the Optistar LE Injectors Use a Fiberoptic "Communication Link"

Claims 8, 22, 31, and 39 of the '602 re-reissue patent require a "fiber optic communications control link" or that "the communication link comprises a fiber optic line". The Optistar injectors have no such fiber optic communication link, but rather, use a shielded electrical cable just as was used in L-F's prior Angiomat 6000 and CT9000 injectors. A shielded cable, like that on the Optistar injectors, is not an equivalent of a fiber optic link, as the differences between the two are substantial; *i.e.*, they do not perform substantially the same function in substantially the same way to achieve substantially the same result.

Fiberoptics use light signals, not electrical signals. Cables carrying electrical signals into the MR room must be shielded to prevent emission of RF interference. Fiberoptics have no such requirement for shielding because they do not emit RF energy. In addition, for fiberoptics to operate the system must include equipment on both sides of the viewing window that converts the electrical signals into light signals and transmits those light signals, and that receives transmitted light signals and converts the received light signals into electrical signals. Moreover, no device in the MRI imaging room can be powered by a fiberoptic link.

By contrast, the Optistar system operates by passing electrical cables through a filter that is installed in a hole in the shielded wall or connected to the penetration panel in the shielded wall. That is, it is connected through a physical breach of the imaging room wall. This cable also carries the power used to operate the Optistar injector in all but the battery powered injector. In addition, the signals carried along the cable (either the control signals or extraneous signals picked up by the cable outside of the imaging room and propagated therealong) will include signals in the frequency range that would be detected and could be carried into the

imaging room. Thus, the cable is passed through a filter to remove these extraneous RF signals. The cable itself is also shielded to reduce the transmission of interfering RF signals into the imaging room. No such filter or shielding is required for a fiberoptic link of the '602 re-reissue patent because the transmission of extraneous RF signals cannot occur with that technology. Moreover, in the Optistar systems there is no need for equipment to convert the electrical signals into light signals, or to convert light signals into electrical signals. Thus, unlike a fiberoptic link, which generates no electromagnetic radiation, the Optistar injector communication link filters the RF signals to be passed into the imaging room and shields the cable to reduce the emission of RF signals that are carried by the cable.

Another substantial difference between the fiberoptic link of the '602 reissue patent and the electrical cable of the Optistar system is that no matter how strong the signal being carried by the fiberoptic link, that signal cannot interfere with the equipment in the imaging room. However, if the strength of the electrical signal being carried by the cable is increased sufficiently, the MR image will eventually be degraded as a result of electromagnetic interference, regardless of the shielding that is used on the cable.

4. Claim 37 Cannot be Infringed Because it is Invalid

Claim 37 is directed to nothing more than an injector used in the performance of an MR procedure that includes "at least two syringes operably engaged with at least one drive mechanism of the injector." There is no requirement of a communication link nor that any link be substantially non-reactive with the magnetic field of the imaging system.

Claim 37 is clearly invalid over the Medex AS 200 brochure, as well as the other prior art showing the desirability of using two syringes in an MRI environment, one for injecting

contrast and the second for a saline flush to ensure all of the contrast has been injected. Because claim 37 is clearly invalid, it cannot be infringed.

G. There Is No Issue of Willful Infringement in this Case

Liebel-Flarsheim introduced its Optistar injector to the marketplace at the beginning of 2000. At that time, Medrad had issued the '036 patent and had filed for a reissue of it, but the reissue was then under examination by the PTO.

L-F had been in negotiations with Nemoto to sell in the United States the Nemoto MRI Injector System that Nemoto had been selling in Japan for a number of years. L-F's investigation and negotiations and its technical review of the Nemoto MRI Injection System extended back a number of years prior to the 2000 introduction of the Optistar injector.

L-F requested and obtained a legal opinion from the law firm of Wood, Herron & Evans, its longtime patent counsel. That opinion is dated October 26, 1998. As stated, the only issued patent was the '036 patent. The opinion analyzed the claims of the '036 patent in detail. Claims 1-7 and 13-22 were all directed to a flexible drive shaft extending between a remote motor box and the injector head to drive the injector. Since the Nemoto injector did not include a flexible drive shaft, but rather used motors located in the injector head, those claims obviously were not infringed. Claim 8 was directed to the fiber-optic communications link. Since the injector to be sold by L-F was going to use shielded cable and not fiber optics, claim 8 again obviously would be not infringed. The opinion also examined the prior art and concluded that the use of fiber optics in an MRI system was shown in a number of domestic and foreign patents and publications, and concluded that claim 8 was invalid. Claim 9 simply recited "a communicating link between the system controller and the infusion apparatus control means", which was shown in the Saini Article and was invalid. Claim 11 depended from claim 9 and

called for the communication link to be infrared based. Since the injector to be sold by L-F was going to use shielded cable and not infrared, claim 11 obviously would not be infringed.

The opinion also looked at the pending claims in the re-issue application, new claims 24-49. The opinion concluded that these claims were invalid in view of the prior art.

Immediately prior to the introduction of the Optistar injector by L-F, management reviewed the Wood, Herron & Evans opinion. In a memo from L-F's Global Marketing Director to the President and the Director of Research and Development dated December 13, 1999, the following was stated:

> You may recall that WHE did a summary opinion letter on October 26, 1998 concerning this patent (TLD, you were copied on this). I have attached key sections of this opinion letter, as it refers to claim 8 and 9, since they are closely linked. As you can see, WHE believes that claim 9, which is the extraordinarily broad claim covering "a communicating link between the system controller and the infusion apparatus control means" is an invalid claim. The fact remains that it is still part of the patent, but they believe that it cannot stand up to scrutiny for the reasons detailed in the letter. They are very confident about this.
>
> Specifically, Medrad had published a report to the RSNA exposing the use of such a communicating link, well in advance of their patent submission. Conveniently, they did not advise the patent office of this at the time of submission; however, they did submit such notification when they applied for reissue recently, and WHE believes that claim 9 should be stricken during the reissue evaluation. Additionally, WHE cites the obviousness of claim 9 (separating the system controller from the infusion apparatus control means with a communicating means). We've been doing it for years in CT, and the MR scanner manufacturers use that separation between console and scanner as part of their basic design.
>
> Obviously, proceeding with the shielded wire is not entirely without risk (as you know, claim 8 makes use of fiber optics more tricky), but it is upon this letter and its rationale that I based my statement that the lawyers had reviewed claim 9, and they were not concerned as long as we used a traditional wire approach.

The '648 re-issue patent issued on April 11, 2000. Medrad almost immediately brought a proceeding against L-F, Mallinckrodt and Nemoto in the ITC and a civil action in this Court. However, in September, 2000 the Administrative Law Judge held the '648 patent to be invalid. The full Commission declined to review the decision of the Administrative Law Judge. Medrad had a right to appeal but, rather than do so, it simply abandoned the ITC proceeding and dismissed its civil action.

The '602 re-reissue patent was issued on March 26, 2002. By that time, the Optistar injector had been on the market for over two years with Medrad having no valid patent. As set forth in the motions for summary judgment, the '612 re-reissue patent was invalid for failure to comply with the statutory prerequisites for a reissue patent. Moreover, the same prior art relied upon in the October 26, 1998 opinion invalidate the claims of the '602 re-reissue patent.

L-F operated prudently in obtaining an opinion of counsel prior to the introduction of the Optistar injector that no claim of Medrad's patents would be infringed and/or that the claims were invalid in view of the prior art.

Nemoto likewise prudently obtained a detailed opinion of counsel regarding the Medrad patents, and in this case regarding the '648 reissue patent, the claims of which are identical to those of the '602 re-reissue patent. That opinion, written in September of 2000, spanned 44 pages and concluded that each of the claims of the '648 reissue patent were invalid and/or not infringed by the Optistar injector. The same prior art recited in that opinion for invalidity of the '648 reissue patent also invalidates the '602 re-reissue patent.

H. This is an Exceptional Case and L-F and Nemoto Are Entitled to an Award of Their Attorney Fees

Medrad brought the present action without a good faith basis to believe that the claims of the '602 re-reissue patent were valid. Indeed, the prior art that clearly invalidates the

claims of the '602 re-reissue patent had been produced by L-F to Medrad in the ITC Action in 2000, or was Medrad's own prior art (*i.e.*, the EM-1), which Medrad did not disclose to the PTO during prosecution of the '602 re-reissue patent. Medrad likewise engaged in egregious inequitable conduct during prosecution of both the '648 reissue patent and the '602 re-reissue patent. This conduct alone is sufficient render the present action exceptional. Being an exceptional case, L-F and Nemoto are entitled to an award of the attorney fees they incurred in defending Medrad's unfounded claims.

II. DEFENSES TO DAMAGES CLAIMS (Redacted information below-confidential)

Medrad overreaches on its damages claim for a "reasonable royalty" on the sales of the accused Optistar injectors outside of the United States (a region for which Medrad concedes it is not entitled to lost profits). Medrad claims to be entitled to a $6,000 per injector royalty, which amounts to between a [redacted] royalty. Such a royalty is unsupportable.

A "reasonable royalty" is to determined based upon a hypothetical negotiation occurring at the time the alleged infringement began, which is April of 2000 when the '648 reissue patent issued. Medrad failed to make its determination in 2000, but rather, based it on activities occurring in 2001 and 2002. A "reasonable royalty" is also to be determined based upon the *Georgia Pacific* factors, which apply in the present case as follows:

1) Rates paid for licenses by others: L-F had entered into an international agreement with Nemoto in 1999 under which L-F paid an effective royalty rate of approximately [redacted] of the net sales price for the Optistar injectors, which is consistent with typical patent license rates;

2) Whether the parties are competitors: Although L-F and Medrad are competitors, there are a large number of competitors in the MR injector market internationally; and

3) The established profitability of the product: Between 2000 and 2004, L-F's gross margin on the Optistar injectors was between [redacted]. Medrad's "reasonable royalty" would substantially exceed L-F's profit.

After consideration of the relevant *Georgia Pacific* factors, and particularly the agreement between L-F and Nemoto, a reasonable royalty in this action for sales of the Optistar injectors outside of the United States would be between $1,200 and $1,500 per injector.

Medrad also improperly seeks to obtain "damages" for the prospective future sales by L-F of ancillary, unclaimed equipment (*i.e.*, syringes and tubing). If L-F pays "damages" to Medrad for the sale of the Optistar injectors, those injectors have become licensed products for which L-F is free to sell the ancillary equipment without additional payment to Medrad.

III. WITNESS LIST

The following is a list of all individuals that L-F and Nemoto will or may call at the trial of this matter:

Witness	Addresss/Telephone Number	Will Call/ May Call	Subject
Karen A. Becker, Ph.D.	Becker & Associates Consulting, Inc. 2001 Pennsylvania Avenue NW Suite 575 Washington, D.C. 20006 (202) 822-1851	May Call	Liability
Robert A. Bell, Ph.D.	3660 Dove Hollow Road Encinitas, California 92024 (858) 759-0150	Will call	Liability
Heidi Berns	Mercy Hospital Department of Radiology 500 Market Street Iowa City, IA 52245 (319) 339-3629	Will call	Liability

Witness	Addresss/Telephone Number	Will Call/ May Call	Subject
Luanne Culbreth	c/o Linda Stimmel, Esq. Stewart & Stimmel 1701 Market Street Suite 318 Dallas, TX 75202 (214) 752-6995	Will call	Liability
Bruce A. Eisenstein, Ph.D.	Drexel University ECE Department 3141 Chestnut Street Philadelphia, PA 19104 (215) 895-2359	Will call	Liability
John Friel	Medrad, Inc. One Medrad Drive Indianola, PA 15051 (412) 767-2400	Will call	Liability
Richard D. Grauer, Esq.	Rader, Fishman & Grauer PLLC 39533 N. Woodward Ave., Suite 140 Bloomfield, MI 48304 (248) 594-0640	Will call	Liability
James H. Goethel	9966 Thornwood Court Cincinnati, Ohio 45241 (513) 777-4574	Will call	Liability
Steven E. Harms, M.D.	University of Arkansas for Medical Sciences 4301 W Markham St. Little Rock, AR 72205 (501) 686-7000	Will call	Liability
Steve Hanley	Mallinckrodt Inc. 675 McDonnell Boulevard St. Louis, Missouri 63134 (314) 654-2000	May call	Liability
Norman A. Jacobs	141 Worthen Road Lexington, MA 02421 (781) 862-2531	Will call	Damages

Witness	Addresss/Telephone Number	Will Call/ May Call	Subject
Brenda Jones	University of Pittsburgh Medical Center 200 Lothrop Street Pittsburgh, PA 15213 (412) 647-8762	Will call	Liability
James E. Knipfer	Mallinckrodt Inc. 675 McDonnell Boulevard St. Louis, MO 63134 (314) 654-2000	May call	Liability
Sean B. Lafferty	Liebel-Flarsheim Company 2111 East Galbraith Road Cincinnati, OH 45237 (513) 761-2700	Will call	Liability
Lawrence Limpus	19225 St. Albans Valley Drive Glencoe, MO 63038 (636) 458-0817	Will call	Liability/ Damages
Julianne Marelli	University of Pittsburgh Medical Center 200 Lothrop Street Pittsburgh, PA 15213 (412) 647-8762	Will call	Liability
Charles Neer	Liebel-Flarsheim Company 2111 East Galbraith Road Cincinnati, OH 45237 (513) 761-2700	Will call	Liability
Glenn Newman	Parente Randolph LLC Two Penn Center Plaza, Suite 1800 Philadelphia, PA 19102 (215) 972-0701	Will call	Damages
Eric Porter	Duke University Medical Center Radiology Department 1531 Hospital North, Box 3808 Durham, NC 27710 (888) 275-9259	Will call	Liability

Witness	Addresss/Telephone Number	Will Call/ May Call	Subject
Mervin Roussell	Radiology Imaging Associates 7801 Old Branch Ave., #300 Clinton, MD 20735 (301) 856-6718	Will call	Liability
Val Runge, M.D.	Scott & White Clinic and Hospital Radiology Department 2410 South 31st Street Temple, TX 76508 (254) 724-2007	Will call	Liability
Sanjay Saini, M.D.	Emory University School of Medicine Radiology Department Emory University Hospital 1364 Clifton Avenue, NE Atlanta, GA 30322 (404) 712-4996	Will call	Liability
Mark Trocki	Medrad, Inc. One Medrad Drive Indianola, PA 15051 (412) 767-2400	Will call	Liability
Gerald Wolf, M.D.	AAI Development Clinical Trials Division Two Vision Drive Natick, MA 01760 (508) 650-0085	Will call	Liability
Steven D. Wolff, M.D.	201 East 69th Street, Apt. 10-O New York, NY 10021 (212) 717-8272	Will call	Liability

IV. DEPOSITION DESIGNATIONS, OBJECTIONS AND COUNTER-DESIGNATIONS TO PLAINTIFF'S DEPOSITION DESIGNATIONS

Attached as Exhibit A is a designation of all witnesses whose testimony L-F and Nemoto expect to present by means of a deposition, including a designation of those portions of the deposition transcripts to be presented. Attached as Exhibit B are Defendants' objections to Medrad's deposition designations. Attached as Exhibit C are Defendants' counter-designations to Medrad's deposition designations.

V. EXHIBIT LIST

Attached as Exhibit D is an identification of each document or other exhibit that L-F and Nemoto expect to offer at trial, or that they may offer at trial if the need arises.

VI. LEGAL ISSUES TO BE ADDRESSED AT THE FINAL PRETRIAL CONFERENCE

For the most part, the "legal issues" listed by Medrad are not legal issues that all, but rather issues of procedure. L-F will be prepared to discuss them at the conference.

L-F agrees that whether inequitable conduct should be tried to the Court or jury is a legal issue. L-F's position is that it should be tried to the jury.

The Court has before it L-F's motion in limine regarding the prior art status of the Metex AS 200 brochure and the Medrad EM-1 operating manual. L-F is filing other motions in limine and will have objections to both Medrad's exhibits and deposition designations.

VII. COPIES OF EXPERT DISCLOSURES MADE BY DEFENDANTS

Attached as Exhibit E is a copy of all expert disclosures made by L-F and Nemoto pursuant to Fed. R. Civ. P. 26(a)(2) with respect to those expert witnesses identified in Section III above pursuant to LR 16.1.4A(3). Those expert reports identified as "Confidential" have not

been submitted for publicly accessible electronic filing pending ruling on Defendants' Motion for Leave to File Supplemental Pretrial Statement Under Seal

Respectfully submitted,

TYCO HEALTHCARE GROUP LP,
MALLINCKRODT INC.,
LIEBEL-FLARSHEIM COMPANY and
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Dated: September 9, 2005

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